

# EXHIBIT A

**SETTLEMENT AGREEMENT AND RELEASE**

**I. PARTIES**

This Settlement Agreement ("Agreement") is entered into this \_\_\_\_ day of \_\_\_\_\_, 2003. The parties to the Agreement are the State of New York and Zeneca Inc. and AstraZeneca Pharmaceuticals LP (collectively and hereinafter referred to as "Zeneca"), which has its headquarters in Wilmington, Delaware, and is a successor to the pharmaceutical business of Zeneca, Inc., and are collectively referred to as the parties. The Parties now agree as follows:

**II. PREAMBLE**

A. WHEREAS, Zeneca is entering into a civil settlement with the United States of America, acting through and/or on behalf of its Department of Justice and the United States Attorney's Office for the District of Delaware, and the Office of the Inspector General of the United States Department of Health and Human Services ("HHS-OIG"); TRICARE Management Activity ("TMA") (formerly known as the Office of the Civilian Health and Medical Program of the Uniformed Services), a field activity of the Office of the Secretary of Defense; the Defense Supply Center Philadelphia, of the Defense Logistics Agency, the United States Department of Defense ("DSCP"); the Railroad Retirement Board ("RRB") (the "Federal Settlement"), and relator in a certain federal False Claims Act lawsuit, as well as settlement agreements with the state of New York and numerous other states (hereinafter the "Participating States"), all of which are intended to resolve civil claims for the conduct alleged in Preamble Paragraph F below;

B. WHEREAS, this Agreement addresses the state of New York's claims against Zeneca for the conduct alleged in Preamble Paragraph F below;

C. WHEREAS, on such date as may be determined by the Court, Zeneca will enter a plea of guilty pursuant to Fed. R. Crim. P. 11(c)(1)(C) to a one count Information alleging a violation of

Title 18, United States Code, Section 371, namely, a conspiracy to violate the Prescription Drug Marketing Act, 21 U.S.C. §§ 333(b) and 331(t) by causing the billing of free drug samples (hereinafter the "Criminal Action");

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D. WHEREAS, at all relevant times, Zeneca marketed and sold the drug Zoladex in various dosages to physicians, health maintenance organizations, hospitals, wholesalers, and others for use in treatment of prostate cancer;

E. WHEREAS, the state of New York alleges that Zeneca caused to be submitted claims for payment for Zoladex to the state's Medical Assistance Program ("Medicaid") established pursuant to Title XIX of the Social Security Act;

F. WHEREAS, the state of New York contends that it has Medicaid-related civil claims against Zeneca under various statutes and the common law for engaging in the following alleged conduct from January 1991 through the present, involving the marketing, sale and pricing of Zoladex for treatment of prostate cancer;

(i) The state of New York contends that certain employees of Zeneca provided free samples of the drug Zoladex to certain physicians, knowing and expecting that those physicians would prescribe and administer the free drug samples to their patients and thereafter illegally bill those free samples to its Medicaid program;

(ii) The state of New York contends that Zeneca knowingly and willfully offered and paid illegal remuneration to certain physicians, physicians' practices, and others in various forms including, for example, free Zoladex, unrestricted educational grants, business assistance grants and services, travel and entertainment, consulting and audit services, and honoraria, to obtain unlawfully orders to purchase the drug Zoladex for treatment of prostate cancer from Zeneca, knowing that reimbursement for the drug would be made by the state's Medicaid program;

(iii) The state of New York contends that Zeneca knowingly and willfully offered and paid illegal remuneration to physicians by marketing Zeneca's "Return-to-Practice" program to physicians to unlawfully induce orders to purchase the drug Zoladex for treatment of prostate cancer, knowing that reimbursement for the drug would be made by the state's Medicaid program. The state of New York further contends that Zeneca's Return-to-Practice program consisted of inflating the Average Wholesale Price ("AWP") used by Medicaid and others for reimbursement of the drug, deeply discounting the price paid by physicians to Zeneca for the drug ("the discounted price"), and marketing the spread between the AWP and the discounted price to physicians as additional profit to be returned to the physician's practice from Medicaid's reimbursements for Zoladex. The state of New York further contends that Zeneca falsely advised physicians that the discounted price could not and should not be reported to Medicaid;

(iv) The state of New York contends that Zeneca engaged in a marketing scheme where it set an AWP for Zoladex at levels far higher than the majority of its physician customers actually paid for the drug when purchasing from Zeneca. As a result, the state of New York contends that Zeneca's customers received reimbursement from the state of New York's Medicaid program at levels significantly higher than the physicians' actual costs or the wholesalers' average price;

(v) The state of New York contends that Zeneca knowingly misreported and underpaid its Medicaid rebates for Zoladex used for treatment of prostate cancer, i.e., the amounts that it owed to the states under the federal Medicaid Rebate Program, 42 U.S.C. §1396r-8. The state of New York further contends that Zeneca was generally required on a quarterly basis to rebate to each state Medicaid program the difference between the Average Manufacturer Price ("AMP") and its "Best Price," as defined by 42 U.S.C. §§ 1396r-8(k)(1) and 1396r-8(c)(1)(C). The state of New York alleges that Zeneca falsely reported to the Centers for Medicare and Medicaid Services

(formerly the Health Care Financing Administration) its Best Price for Zoladex used for treatment of prostate cancer because Zeneca calculated its Best Prices for Zoladex without accounting for off invoice price concessions provided in various forms including, for example, cash discounts in the form of grants, services, free goods contingent on any purchase requirement, volume discounts and rebates. As a result, the state of New York contends that Zeneca misreported and underpaid its Medicaid rebates to the states under the Medicaid Rebate Program.

Zeneca's conduct alleged in Preamble Paragraph F is hereinafter referred to as the "Covered Conduct." The state of New York contends that its Medicaid program was damaged as a result of the Covered Conduct;

G. WHEREAS, the state of New York contends that it has administrative and civil claims against Zeneca for administrative and monetary penalties under state and federal law for the Covered Conduct;

H. WHEREAS, other than such admissions as Zeneca makes in connection with its plea in the Criminal Action, Zeneca denies the remaining allegations of the state of New York as set forth herein and in any civil action filed by the state of New York;

I. WHEREAS, to avoid the delay, expense, inconvenience and uncertainty of protracted litigation of these claims, the Parties mutually desire to reach a full and final settlement as set forth below.

### **III. TERMS AND CONDITIONS**

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants, and obligations in this Agreement, and for good and valuable consideration, receipt of which is hereby acknowledged, the Parties agree as follows:

1. Zeneca agrees to pay to the United States and the Participating States, collectively, the sum of two hundred ninety one million, twenty-seven thousand, eight hundred forty-four dollars (\$291,027,844), as set forth below ("Settlement Amount"). This sum shall constitute a debt immediately due and owing to the United States and the Participating States on the effective date of this Agreement. This debt is to be discharged by payments to the United States and the Participating States, under the following terms and conditions:

A. Zeneca shall pay to the United States the sum of two hundred seventy nine million, eight hundred twenty-two thousand, eight hundred forty dollars (\$279,822,844), plus simple interest at the rate of 6% in an amount of (\$45,998.28) for each day following the effective date of this Agreement before complete payment is made (the "Federal Settlement Amount"). The Federal Settlement Amount shall be paid pursuant to the civil settlement agreement entered between Zeneca and the United States (the "Federal Agreement").

B. Zeneca shall pay to the Participating State Medicaid programs the sum of eleven million, two hundred five thousand dollars (\$11,205,000), plus simple interest at the rate of 6% in an amount of (\$1,841.92) for each day following the effective date of the Federal Agreement until complete payment is made (the "State Settlement Amount"). This State Settlement Amount shall be paid to an escrow account pursuant to the State Settlement Agreement no later than seven business days after Zeneca receives written payment instructions from the negotiating team for the Participating States and following the latest date on which the following occurs: (1) the Federal Agreement is fully executed by the Parties and delivered to Zeneca's attorneys, (2) the stipulated dismissals described in the Federal Agreement are filed and copies provided to Zeneca's attorneys, or (3) the Court accepts the Fed. R. Crim. P. 11(c)(1)(C) guilty plea in connection with the Criminal Action as described in Preamble Paragraph C and imposes the agreed-upon sentence. The escrow

account into which Zeneca shall deposit the State Settlement Amount shall be an account under the custody and control of a Medicaid Fraud Control Unit, which shall be designated by the state negotiating team. This Medicaid Fraud Control Unit shall act as Escrow Agent and shall retain such funds until their release in accordance with the payment terms set forth in subparagraph D below.

C. The total portion of the Settlement Amount paid by Zeneca in settlement for alleged injury to the Medicaid program for the state of New York is \$4,931,188.86, consisting of a portion paid to the state of New York under this agreement and another portion paid to the federal government as part of the Federal Settlement Agreement. The individual portion of the State Settlement Amount allocable to the state of New York, and which may be withdrawn by the state of New York from escrow pursuant to this Agreement is \$2,544,796.23 (the "Individual State Settlement Amount"), plus any accrued interest on that portion of the State Settlement Amount. The portion of the Federal Settlement Amount allocable to the state of New York is \$2,386,392.63.

D. The state of New York shall be entitled to disbursement of its Individual State Settlement Amount from the escrow account ten days after the Escrow Agent has received fully executed state settlement agreements from all of the participating states, or, in the alternative, when the state negotiating team and Zeneca agree that the Individual State Settlement Amounts shall be disbursed.

E. If Zeneca's agreed upon guilty plea pursuant to Fed. R. Crim. P. 11(c)(1)(C) in the Criminal Action described in Preamble Paragraph C is not accepted by the Court or the Court does not impose the agreed upon sentence for whatever reason, this Agreement shall be null and void at the option of either the state of New York or Zeneca. If either the state of New York or Zeneca exercises this option, which option shall be exercised by notifying all Parties, through counsel, in writing within ten business days of the date on which the party receives actual notice of the Court's

decision, the Parties will not object and this Agreement will be rescinded. If this Agreement is rescinded, Zeneca agrees that the period of time between January 10, 2003, and thirty days after rescission of this Agreement shall be excluded for the purpose of considering any time-related defenses, including but not limited to those defenses based in whole or in part on a statute of limitation or on a theory of laches.

2. In consideration of this Agreement and payment set forth herein and subject to the exceptions from release set forth in Paragraph 3, the state of New York, on behalf of itself, and its officers, agents, agencies, and departments, releases and discharges Zeneca, its predecessors, successors, subsidiaries, partners, joint venture owners, and their corporate parents and affiliates, predecessors, successors and assigns, and their current and former directors, officers and employees from any civil or administrative claims for Medicaid damages or penalties that the state of New York has or may have relating to the Covered Conduct as defined in Preamble Paragraph F. The payment of the Settlement Amount fully discharges Zeneca from any obligation to pay Medicaid-related restitution, damages, and/or any fine or penalty to the state of New York for the Covered Conduct.

3. Notwithstanding any term of this Agreement, the state of New York specifically does not herein release any person or entity, including Zeneca, its predecessors, successors, subsidiaries, partners, joint venture owners, and their corporate parents and affiliates, predecessors, successors and assigns, and their current and former directors, officers, and employees from any and all of the following: (a) any criminal, civil or administrative claims arising under state of New York revenue codes; (b) any criminal liability not specifically released by this Agreement; (c) any liability to the state of New York (or any agencies thereof) for any conduct other than the Covered Conduct; (d) any claims based upon obligations created by this Agreement; (e) except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care



programs; (f) any express or implied warranty claims or other claims for defective or deficient products and services provided by Zeneca; (g) any claims for personal injury or property damage or for other consequential damages arising from the Covered Conduct; (h) any claim based on a failure to deliver items or services due; or (i) any civil or administrative claims against individuals, including current and former directors, officers, and employees of Zeneca, its predecessors, subsidiaries, partners, joint venture owners, and their corporate parents and affiliates, who, related to the Covered Conduct, receive written notification that they are the target of a criminal investigation, are criminally indicted or charged, or are convicted, or who enter into a criminal plea agreement; or (j) any reporting of AWP for Zolodex to First Data Bank or any other national reporting service for use in Medicaid reimbursement submitted subsequent to the effective date of this Agreement.

4. In consideration of the obligations of Zeneca set forth in this Agreement and conditioned upon Zeneca's payment in full of the Settlement Amount, the state of New York agrees to release and refrain from instituting, directing, recommending or maintaining any administrative claim or any action seeking exclusion from the state of New York's Medicaid program against Zeneca, its predecessors, successors, subsidiaries, partners, joint venture owners, their corporate parents and affiliates, predecessors, successors and assigns for the Covered Conduct or for Zeneca's conviction in the Criminal Action. Nothing in this Paragraph precludes the state of New York from taking action against Zeneca in the event that Zeneca is excluded by the federal government, or for conduct and practices other than the Covered Conduct or the conviction in the Criminal Action. Zeneca acknowledges that the state of New York does not have the authority to release Zeneca from any claims or actions which may be asserted by private payors or insurers, including those that are paid on a capitated basis for providing health care to the state's Medicaid program.

5. This agreement is expressly conditioned upon resolution of the Criminal Action. In consideration of the Criminal Action, the Medicaid Fraud Control Unit of the state of New York agrees that it shall not prosecute or refer for investigation or prosecution to any agency Zeneca, its predecessors, successors, subsidiaries, partners, joint venture owners, and their corporate parents and affiliates, predecessors, successors and assigns for the Covered Conduct.

6. Zeneca fully and finally releases the state of New York, its agencies, employees, servants, and agents from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) which Zeneca has asserted, could have asserted, or may assert in the future against the state of New York, its agencies, employees, servants, and agents, related to or arising from the investigation and prosecution of Covered Conduct up to the effective date of this Agreement.

7. Zeneca waives and will not assert any defenses it may have to any criminal prosecution or administrative action relating to the Covered Conduct which defenses may be based in whole or in part on a contention that, under the Double Jeopardy Clause of the Fifth Amendment of the Constitution or Excessive Fines Clause of the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. Zeneca agrees that this Agreement is not punitive in purpose or effect.

8. The Settlement Amount that Zeneca must pay pursuant to Paragraph 1 above will not be decreased as a result of the denial of claims for payment now being withheld from payment by the state of New York's Medicaid program where such denial resulted from the Covered Conduct. If applicable, Zeneca agrees not to resubmit to the state of New York's Medicaid program any previously denied claims, which denials were based on the Covered Conduct and agrees not to appeal any such denials of claims.

9. Zeneca agrees to the following:

(a) Unallowable Costs Defined: that all costs (as defined in the Federal Acquisition Regulations (FAR) 31.205-47 and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§1395-1395ggg and 1396-1396v, and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Zeneca, its present or former officers, directors, employees, shareholders, and agents in connection with: (1) the matters covered by this Agreement and the related plea agreement; (2) the United States' and the state of New York's audit and civil and criminal investigation of the matters covered by this Agreement; (3) Zeneca's investigation, defense, and any corrective actions undertaken in direct response to the United States' and the state of New York's audit and civil and criminal investigation in connection with the matters covered by this Agreement (including attorney's fees); (4) the negotiation and performance of this Agreement and the plea agreement; (5) the payment Zeneca makes to the United States and the Participating States pursuant to this Agreement and any payments that Zeneca may make to relators; (6) the negotiation of the Corporate Integrity Agreement (CIA), and the obligations undertaken pursuant to the CIA to: (i) retain an independent review organization to perform annual reviews as described in Section III of the CIA; and (ii) prepare and submit reports to the HHS-OIG, are unallowable costs on Government contracts and under the Medicare Program, Medicaid Program, Railroad Retirement, TRICARE, DOD, and Federal Employees Health Benefits Program (FEHBP). However, nothing in this paragraph affects the status of costs that are not allowable based on any other authority applicable to Zeneca. (All costs described or set forth in this Paragraph 9(a) are hereafter, "unallowable costs").

(b) Future Treatment of Unallowable Costs: If applicable, these unallowable costs will be separately estimated and accounted for by Zeneca, and Zeneca will not charge such unallowable costs directly or indirectly to any contracts with the United States or any State Medicaid

Program, or seek payment for such unallowable costs through any cost report, cost statement, information statement, or payment request submitted by Zeneca or any of its subsidiaries to the Medicare, Medicaid, TRICARE, DOD, Railroad Retirement or FEHBP Programs.

(c) Treatment of Unallowable Costs Previously Submitted for Payment: If applicable, Zeneca further agrees that within 60 days of the effective date of this Agreement, it will identify to applicable Medicare, Railroad Retirement and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid, DOD, VA and FEHBP fiscal agents, any unallowable costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid Program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Zeneca or any of its subsidiaries, and will request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. Zeneca agrees that the United States and the state of New York, at a minimum, will be entitled to recoup from Zeneca any overpayment plus applicable interest as a result of the inclusion of such unallowable costs on previously-submitted cost reports, information reports, cost statements, or requests for payment. Any payment due after the adjustments have been made shall be paid to the United States or the state of New York pursuant to the direction of the Department of Justice, and/or the affected agencies. The state of New York reserves its rights to disagree with any calculations submitted by Zeneca or any of its subsidiaries on the effect of inclusion of unallowable costs (as defined in this Paragraph) on Zeneca or any of its subsidiaries' cost reports, cost statements, or information reports. Nothing in this Agreement shall constitute a waiver of the rights of the United States or the state of New York to examine or reexamine the unallowable costs described in this Paragraph.

10. If applicable, Zeneca agrees that it will not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents or sponsors. Zeneca waives any causes of action against these beneficiaries or their parents or sponsors based upon the claims for payment covered by this Agreement.

11. Zeneca expressly warrants that it has reviewed its financial situation and that it currently is solvent within the meaning of 11 U.S.C. Section 547(b)(3), and will remain solvent following its payment to the state of New York hereunder. Further, the Parties expressly warrant that, in evaluating whether to execute this Agreement, the Parties (i) have intended that the mutual promises, covenants and obligations set forth herein constitute a contemporaneous exchange for new value given to Zeneca, within the meaning of 11 U.S.C. Section 547(c)(1), and (2) have concluded that these mutual promises, covenants and obligations do, in fact, constitute such a contemporaneous exchange.

12. This Agreement is intended to be for the benefit of the Parties only, and by this instrument the Parties do not release any claims against any other person or entity, including but not limited to any individual or entity that purchased Zoladex from Zeneca.

13. Nothing in any provision of this Agreement constitutes an agreement by the state of New York concerning the characterization of the Settlement Amount for purposes of state internal revenue codes or the United States Internal Revenue Code.

14. In addition to all other payments and responsibilities under this agreement, Zeneca agrees to pay all reasonable travel costs and expenses (including distribution costs) of the state negotiating team. Zeneca will pay this amount by separate check or wire transfer made payable to the National Association of Medicaid Fraud Control Units after all Participating States execute this Agreement, or as otherwise agreed upon by the state negotiating team and Zeneca.

15. Zeneca agrees to cooperate completely and truthfully with the state of New York's on-going investigation of third parties for alleged violations of state and federal law arising out of its investigation. Zeneca understands and agrees that such cooperation shall include the following:

(a) prompt production of any non-privileged document or record in the possession, custody or control of Zeneca relating to the subject matter of the investigation. In connection with this, Zeneca shall provide such technical assistance as is necessary and reasonable to facilitate the state of New York's access to any non-privileged computerized information covered by this subparagraph:

(b) taking all reasonable measures available to Zeneca to ensure that present and former officers, directors, agents and employees of Zeneca cooperate truthfully and completely in connection with the on-going investigation; and

(c) taking all reasonable measures available to Zeneca to make all present and former employees of Zeneca available for interviews by law enforcement personnel, upon reasonable notice.

Provided, however, notwithstanding any provision of this Agreement, that Zeneca is not required to request of its present or former employees or agents that they forego seeking the advice of an attorney nor that they act contrary to that advice, and that Zeneca is not and will not be required to waive the attorney-client privilege, the protection of the work product doctrine, or any other privilege or protection from disclosure.

16. Zeneca represents that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

17. Zeneca has entered into a CIA with HHS-OIG. Zeneca acknowledges that the state of New York may gain access to and use pricing information provided by Zeneca under the CIA,

provided that the state of New York meets its obligations relating to the use and confidentiality of that information as set forth in this Agreement. Zeneca acknowledges that the CIA does not preclude the state from taking any appropriate action against Zeneca for future conduct under the state of New York's laws. The state of New York hereby agrees to abide by all confidentiality provisions and restrictions contained in the CIA as allowed by state law and afford all such information the maximum degree of confidentiality permitted by law.

18. Zeneca shall report directly to the Medicaid Program for the state of New York the average sale price, as defined below, for the following currently marketed drugs: Cefotan, Elavil Injection<sup>1</sup>, Faslodex, Foscavir, Merrem, Tenormin Injection, Xylocaine Injection, Zolodex, and all other newly developed injectible products which are primarily marketed and sold by Zeneca to individual medical practitioners/clinics for in-office administration and directly billed by the practitioner/clinic to health care insurers, including federal health care programs (hereinafter "Covered Products").

(a) Average Sale Price Definition: For purposes of this Agreement, "Average Sale Price" means, with respect to each dosage form, strength and volume of the Covered Products (without regard to any special packaging, labeling, or identifiers on the dosage form or product or package) the average of all final sales prices charged by Zeneca for the product in the United States to all purchasers, excluding those sales exempt from inclusion in the calculation of "Best Price" for Medicaid Drug Rebate purposes, pursuant to 42 U.S.C. § 1396r-8, and excluding identifiable direct sales to hospitals. (Those purchasers for which the sales are included in the calculation of Average Sale Price are hereafter referred to as the "Relevant Purchasers.") The prices identified in the

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<sup>1</sup> As of February 2003, AstraZeneca no longer makes or sells Elavil injection. Consequently, AstraZeneca may be limited or unable to report average sale price for this product in the future.



calculation of the Average Sale Price should be net of all the following: volume discounts; prompt pay discounts; cash discounts; charge backs; short-dated product discounts; free goods; rebates<sup>2</sup>; and all other price concessions provided by Zeneca to any Relevant Purchaser that result in a reduction of the ultimate cost to the purchaser. Notwithstanding the foregoing, the Average Sale Price shall not include the value of bona fide charity care or bona fide grants.

Zeneca shall report the Average Sale Price by National Drug Code ("NDC") for each Covered Product identified by Zeneca's NDC. The Average Sale Price reported shall be properly weighted to reflect the volume of sales at each sale price, *i.e.*, for each NDC, the price reported shall be an average per unit price determined by dividing the sum of all final prices charged by Zeneca to a Relevant Purchaser, net of all price reductions identified above, for a Covered Product in a quarter by the total number of units of that product sold in that quarter.

(b) Time Frame: Except as otherwise noted below, forty five (45) days after the last day of each calendar quarter, Zeneca shall report, in accordance with section 18(a) above, the average sale prices of each of its Covered Products identified by Zeneca's NDC to: (1) the Medicaid programs of those States who have executed a State Settlement Agreement with Zeneca; and (2) First DataBank Inc.<sup>3</sup> solely for the purpose of reporting pricing information based on those Average Sale Prices to the Medicaid Programs of those States that have executed a state settlement agreement. The first such report of Average Sale Prices shall be made no later than 45 days after the end of the

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<sup>2</sup> The term "rebate" as used in this paragraph does not include any payments made by Zeneca to the States pursuant to the Medicaid Drug Rebate Program (42 U.S.C. § 1396r-8).

<sup>3</sup> If appropriate to reflect changes in the sources from which the Medicaid programs for the Participating States receive pricing information, Zeneca agrees that, upon the receipt of a written request by any of the Participating States, Zeneca will report the required information to a drug pricing reporting source other than, and in addition to, FirstDataBank, provided that the price reporting source agrees to protect the confidentiality of Zeneca's pricing information in a written agreement containing reasonable provisions equivalent to the confidentiality provisions governing the submission of pricing information to First DataBank.



first full calendar quarter following the Effective Date of the CIA. The Average Sale Price reporting obligations under this agreement may be subject to modification consistent with a change in federal or state statutory or regulatory requirements for the submission of price information by pharmaceutical manufacturers.

(c) Certification: With each report of Average Sales Price information Zeneca sends to the Medicaid Program for the state of New York, an appropriate employee or agent of Zeneca will certify that price information reported has been reported to First DataBank, or any successor or alternative reporting agency, and that the information has been calculated in accordance with the methodology described in this Agreement. Said certification shall be in the form annexed to this Agreement as Exhibit "A." Zeneca agrees that this certification by an appropriate employee or agent of Zeneca constitutes a certification by Zeneca.

(d) Document Retention: Zeneca shall retain all supporting work papers and documentation relating to the average sale price of its Covered Products for six years after the effective date of the CIA, and, to the extent not protected by appropriately asserted privileges, shall make such documentation available for inspection by the MFCU for the state of New York, or a duly authorized representative of the MFCU, pursuant to the confidentiality provisions set forth in paragraph 20 below.

(e) Time Period: Zeneca agrees to submit Average Sale Price in accordance with this Agreement for a period of five years from the effective date of the CIA.

19. (a) Zeneca and the state of New York acknowledge that Zeneca considers the pricing information provided by Zeneca to be confidential commercial information and proprietary trade secrets that if disclosed may cause substantial injury to the competitive position of Zeneca. It is further understood that all information provided by Zeneca shall be made available to the state of

New York's MFCU upon request. The state of New York hereby agrees to afford to the pricing information disclosed by Zeneca the maximum degree of confidentiality permitted by law.

(b) The Medicaid Program of the state of New York has been advised by the MFCU of the purpose and use of this information. Without surrendering any legal right to contest the use of this information, Zeneca acknowledges that this information may be relied upon by the state of New York in establishing reimbursement rates for Zeneca's products, provided however the state of New York will not change reimbursement rates for any Zeneca product based on this information without conducting meaningful review for all government-reimbursed therapeutically similar products.

20. Unless otherwise stated in writing subsequent to the execution of this Agreement, all notifications and communications made pursuant to this Agreement shall be submitted to the entities listed below:

**STATE PHARMACY MANAGER**  
**[For the submission of Average Sale Price Data]:**

Office of Medicaid Management  
New York State Department of Health  
Bureau of Program Guidance  
99 Washington Avenue  
Suite 606  
Albany, NY 12210-2806

**STATE MEDICAID FRAUD CONTROL UNIT**  
**[For legal notices and other purposes]:**

MFCU of New York  
Office of the Attorney General  
120 Broadway, 13th Fl.  
New York, NY 10271

**ZENECA**

Glenn Engelmann  
Vice President, General Counsel  
And Secretary  
Zeneca, Inc.

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21. This Agreement is governed by the laws of the state of New York. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties under this Agreement will be the appropriate court having jurisdiction and venue in the state of New York.

22. The undersigned Zeneca signatory represents and warrants that he is authorized by the Board of Directors of AstraZeneca PLC, the parent corporation of AstraZeneca Pharmaceuticals, LP, to execute this Agreement. The undersigned state of New York signatories represent that they are signing this Agreement in their official capacities and they are authorized to execute this Agreement on behalf of the state of New York through their respective agencies and departments.

23. This Agreement is effective on the date of signature of the last signatory to the Agreement.

24. This Agreement shall be binding on all successors, transferees, heirs and assigns of the Parties.

25. This Agreement constitutes the complete agreement between the Parties with regard to the Covered Conduct. This Agreement may not be amended except by written consent of the Parties.

26. This Agreement may be executed in counterparts, each of which shall constitute an original and all of which shall constitute one and the same Agreement.

THE STATE OF NEW YORK

DATED: 8-14-03

\_\_\_\_\_  
State of New York  
Office of the Attorney General  
Medicaid Fraud Control Unit

BY: William J. Conisley  
Title Director

**ASTRAZENECA PHARMACEUTICALS LP**

By: \_\_\_\_\_  
Glenn Engelmann  
Vice President, General Counsel  
And Compliance Officer  
AstraZeneca Pharmaceuticals LP

Dated: \_\_\_\_\_

By: John C. Dodds  
JOHN C. DODDS  
Morris, Lewis & Bockius LLP  
1701 Market Street  
Philadelphia, PA 19103-2921  
Counsel to AstraZeneca Pharmaceuticals, LP

Dated: 12/3/03

ZENECA, INC.

By: \_\_\_\_\_  
Glenn Engelmann  
Vice President, General Counsel  
And Secretary  
Zeneca, Inc.

Dated: \_\_\_\_\_

By: John C. Dodds  
John C. Dodds  
Morgan, Lewis & Bockius, LLP  
1701 Market Street  
Philadelphia, PA 19103-2921  
Counsel to Zeneca, Inc.

Dated: 12/3/03

EXHIBIT 'A' CERTIFICATION FORM

**CERTIFICATION**

The undersigned, an agent of AstraZeneca Pharmaceuticals LP, hereby certifies that the attached average sale price information has been communicated to First Databank or any successor or alternative reporting agency, and that it has been calculated in accordance with the methodology described in the State Settlement Agreement and as further described in AstraZeneca Pharmaceuticals LP's Corporate Integrity Agreement with the Office of Inspector General of the United States Department of Health and Human Services.

Signed \_\_\_\_\_

Title \_\_\_\_\_

Date \_\_\_\_\_